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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,464	08/13/2001	William J. Boyle	ACS-57080	6454

24201 7590 05/22/2006

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER

MCCORKLE, MELISSA A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/928,464	Applicant(s) BOYLE ET AL.	
	Examiner Melissa A. McCorkle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 6,9-28,30 and 34-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-8, 29, 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7, 29, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Curelaru et al (4,581,019). Curelaru et al discloses a delivery sheath (fig 2) comprising an elongate tube having a proximal end (1) and a distal end (2), and a resealable longitudinal joint (col 3 lines 14-18), the longitudinal joint further comprising a first side and a second side (fig 6), the first side including a protrusion having a neck leading to a head (fig 6), the head (7) being larger than the neck (9), and the second side including an opening leading to a cavity (2), the opening being smaller than the head (7) of the first side and at least as large as the neck of the first side (fig 6), and the cavity being within a range of slightly smaller to larger than the head of the first side (fig 6). Curelaru et al discloses a single lumen formed within the elongate tube (fig 6), the longitudinal joint extends throughout an entire length of the sheath (fig 5 – part 13), the longitudinal joint extends from a proximal end of the sheath to a position proximal a distal end of the sheath (fig 5); the longitudinal joint has a depth extending from an external surface of the sheath to a surface of the lumen (col 4 lines 39-41).
3. Regarding claims 29, 31, and 33, Curelaru et al discloses a delivery system comprising a sheath (fig 2) including an elongate tube (1) having at least one lumen (2)

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extending a length of the sheath (fig 2, 5) and a self-resealable longitudinal joint (fig 5 and col 3 lines 14-18) a guide wire distributed throughout the length of at least one lumen (fig 9), a handle disposed at a proximal portion of the sheath (11 on fig 5), a device coupling the proximal portion of the sheath to a distal portion of the handle (fig 5, fig 9), a device configured to split the longitudinal joint and to allow the sheath to be removed from the guidewire (9); the splitting device further comprising a blade (9) aligned with a longitudinal axis of the ring (15) and being coupled to the surface of the lumen of the ring (fig 9), a height of the blade being sufficient to extend into the lumen of the sheath (9 is larger than lumen) and including a distal edge for cutting the sheath during relative movement between the ring and the sheath (col 4 lines 56-64), the device coupling the proximal portion of the handle is split along the length of the device (fig 5, fig 9, fig 14).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curelaru et al (4,581,019) in view of Campbell et al (5,868,704). Curelaru et al discloses applicant's basic inventive concept of a convertible delivery medical system for medical device, substantially as claimed, with the exception of specifically stating that the lumen is capable of being pressurized up to and over 8 atm, as well as the ring of the delivery system further comprising a guide mandrel. Campbell et al shows both of these features to be old in the medical delivery devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Campbell et al to modify the delivery device of Curelaru et al to make the lumen capable of being pressurized up to and over 8 atm (col 15, lines 18-23) so that it can withstand normal inflation and deflation pressures when the device is in use. It also would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Campbell et al to modify the delivery device of Curelaru et al to add a guide mandrel (col 5 lines 8-12) coupled to the edge of the blade, and configured to be positioned within the lumen of the sheath for the purpose of helping the tube to form.

Response to Arguments

6. Applicant's arguments filed 2/16/06 have been fully considered but they are not persuasive. The Curelaru patent, as stated above, is able to be resealed. The method of resealing does not need to be disclosed in order for the device to be resealable. The structure is not different from Applicant's claimed invention. Furthermore, the previous

art is not withdrawn as anticipatory, rather, this art is relied on in addition to the other art previously used in the case.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle
Examiner
Art Unit 3763



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